

**Remarks**

**Rejection under 35 USC 102**

Claim 1 was rejected under 35 USC 102(b) as being anticipated by US Patent 5,836,962 to Gianotti (hereinafter Gianotti). Claims 1 through 5, 13 and 18 through 20 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 4,646,742 to Packard et al. (hereinafter Packard).

By the present response, independent claim 1 has been amended to additionally recite an expandable frame attached to the membrane and reinforcing fiber composite structure. In this way, the frame, when in an expanded shape, holds the membrane in a desired shape. Support for this amendment can be found in numerous locations within the originally-filed specification, including original claim 2 (for the frame), page 38, line 5, page 44, lines 2 through 5, and page 46, line 30 (for the expandable nature of the frame). Dependent claim 2 has also been amended to recite that the expandable frame of amended claim 1 is of a metallic structure. Support for this amendment can be found in numerous locations within the originally-filed specification, such as page 2, line 21, page 3, line 10 and page 6, lines 1 through 3. Original claims 48 and 55 also recite a frame that is attached to at least one of the reinforcing fibers and the composite structure.

Gianotti does not teach or suggest such a feature, and in fact is entirely silent as to the use of an expandable frame, irrespective of purpose. As such, it can no longer be relied upon to meet the minimum established by MPEP 2131 for a valid anticipatory rejection. Furthermore, because "[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art" *In re Miller*, 169 USPQ 597, 600 ((CCPA 1971), quoting *In re Wilson*, 165 USPQ 494, 496 (CCPA 1970)), and the composite fiber of Gianotti makes no mention of a fiber-reinforced membrane or an expandable frame to which such membrane is attached, it must be withdrawn as an anticipatory reference under the authority cited above.

Likewise, Packard makes no mention of a fiber-reinforced membrane composite structure attached to an expandable frame such that the composite structure relies upon the frame (when expanded) to hold the membrane in a desired shape. At most, Packard includes one or more circumferential hoop-like bands **60** for reinforcing an expandable elastomeric balloon **24**. In fact, there is not a single mention of a frame, cage, basket or related structure with which to give a fiber-reinforced expanded membrane a desired shape. What the Examiner refers to as a frame (the outer tube **12** shown in exemplary fashion in FIGS. 1 and 3) is in fact a compressed fluid (typically air) delivery conduit. In situations where the elastomeric balloon **24** needs to be expanded, the compressed fluid is passed through apertures **22** formed in outer tube **12** to allow expansion of the balloon **24**. This air delivery conduit in no way correlates to the claimed frame of amended claim 1 or original claims 48 and 55, examples of which are shown in the original specification as frames **450** (FIGS. 30 and 31), **550** (FIG. 32), **650** (FIGS. 33 and 35), **750** (FIGS. 36A and 36B), **850** (FIG. 37), **950** (FIG. 39) and **1050** (FIG. 40A). The expandable nature of the claimed frame is shown with even more specificity in FIGS. 36A and 36B. Because anticipation requires the presence of a single prior art reference which discloses each and every element of the claimed invention arranged as in the claim, and Packard is deficient with regard to at least the claimed frame limitation of amended claim 1 or original claims 48 and 55, Packard must be withdrawn as an anticipatory reference.

**Rejection under 35 USC 103**

Claims 1-5, 8, 9, 13, 15, 18-21, 41, 42, 48, 51, 52 and 55-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,371,971 to Tsugita et al. (hereinafter Tsugita) in view of Gianotti. Claims 6, 10, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsugita in view of Gianotti as applied to claims above, and further in view of US Patent 5,814,064 to Daniel et al. (hereinafter Daniel).

As mentioned above, each of independent claims 1, 48 and 55 either have been amended to recite a frame with which to attach the fiber-reinforced membrane, or have originally recited such feature. Tsugita teaches a vascular filter with either a mesh structure **25** (shown, for

example, in FIGS. 1A through 1D, and described at column 7, line 15) or a membrane (described at column 7, lines 17 through 23) that may be continuous with holes drilled therein. The Examiner admits in numbered paragraph 9 of the Office Action that Tsugita does not disclose reinforcement fibers coupled to a membrane to form a composite structure, and then attempts to rectify this shortcoming by grafting a composite filament of Gianotti with either the mesh or membrane of Tsugita. According to the patentee in Gianotti, an important attribute of the so-called composite filament is that each of the filaments **1** of Gianotti are made up of reinforcement fibers **4** embedded in matrix (called "support" by the patentee) **3** to "achieve a high flexural rigidity", as discussed (among other places) at column 2, line 4 of Gianotti. As such, the composite structure being taught by Gianotti clearly is limited to not just a wire, cable or the like, but to ones with a high degree of stiffness and flexural rigidity. Such so-called composite structure is readily distinguished from the composite structure of the claimed device, as there is nothing in the composite fiber of Gianotti to indicate that a composite structure involving a fiber reinforcing a membrane is formed.

As such, the present combination of Gianotti and Tsugita fails to establish a *prima facie* case of obviousness, as together they do not teach every aspect of the claimed invention in the manner required by MPEP 2143.03. Specifically, there is nothing in the combination to teach or suggest a fiber used to reinforce a membrane to form a composite structure corresponding to those claims. This lack of teaching of all of the features arranged in the manner claimed and disclosed by the Applicant means that the Examiner's assertion is mere conjecture, and that such conjecture is insufficient for the Examiner to discharge his or her burden to establish a *prima facie* case under the authority set forth in *Graham v. John Deere*, 148 USPQ 459 (1966).

Even more importantly, the use of the extremely rigid composite fiber of Gianotti is incompatible with the composite structure recited in claim 1 of the present application, as various places of the original specification thereof expressly notes that the reinforcement fibers have enough flexibility to allow hinging at the points of attachment to the proximal frame to give the resulting composite membrane extreme flexibility and elasticity in bending, along with the high

strength and prevention of crack propagation through the membrane material. Thus, not only is there no indication that the high rigidity reinforced fibers of Gianotti are suitable for use with the mesh or membrane of Tsugita to produce the claimed invention, there is more than ample evidence to indicate that the features relied upon by the Examiner in the two disparate references actually teach away from one another and the claimed device. Because another of the requirements under MPEP 2143 (specifically MPEP 2143.01) is that there is some suggestion or motivation to modify that reference's teachings, and a well-established example of a *lack* of such motivation is when the references teach away from each other or the claimed invention, any such teaching away is a *per se* demonstration of lack of *prima facie* obviousness. See, e.g., *In re Dow Chemical Co.*, 5 USPQ2d 1529 (Fed. Cir. 1988). Because a "prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention", *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 220 USPQ 303 (Fed. Cir. 1983), the high rigidity composite filaments of Gianotti would deprive the membrane or mesh of Tsugita of the flexibility needed to achieve the blood perfusion capabilities of the claimed device. Thus, one of ordinary skill in the composite structure art would not look to the high rigidity filaments of Gianotti to improve the structural attributes of Tsugita in a way needed to satisfy the needs met by the claimed device. As such, the Examiner's attempted combination is just the sort of teaching away that is prohibited in MPEP 2143.01, and for reasons entirely independent of the shortcomings discussed above in conjunction with MPEP 2143.03, is not a valid basis for rejection of any of independent claims 1, 48 and 55. Because Daniel does nothing to correct Tsugita's and Gianotti's inability to satisfy a *prima facie* case of obviousness, any rejection relying upon its inclusion is also improper.

**Conclusion**

Having shown that aspects of the present rejection based on the cited references is not compatible with accepted case law and USPTO practice, the Applicant respectfully submits that the present rejection for independent claims 1, 48 and 55, as well as all of the claims that depend from them, be withdrawn. Furthermore, the Applicant respectfully requests that a finding of patentability for all of the claims be issued. The Examiner is encouraged to contact the undersigned to resolve efficiently any formal matters or to discuss any aspects of the application or of this response. Otherwise, early notification of allowable subject matter is respectfully solicited.

Respectfully submitted,  
DINSMORE & SHOHL LLP

By \_\_\_\_\_  
John D. Reed  
Registration No. 46,506

One Dayton Centre  
One South Main Street, Suite 1300  
Dayton, Ohio 45402-2023  
Telephone: (937) 449-6453  
Facsimile: (937) 449-6405  
JDR/